

SUPREME COURT: STATE OF NEW YORK
COUNTY OF NEW YORK

CHARLES DODGSON, et ux. ELIZABETH J.
DODGSON, and ROSEANNA M. ROBINSON,

07107916

Plaintiffs,

vs.

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, CARDIAC PACEMAKERS, INC.,
and BOSTON SCIENTIFIC CORPORATION,

Defendants.

COMPLAINT

Index No.:

FILED

JUN 06 2007

COUNTY CLERK'S OFFICE
NEW YORK

Plaintiffs, by and through their counsel, the Law Office of Ronald R. Benjamin, hereby
allege, upon information and belief, the following claims against defendants:

1. Plaintiffs CHARLES DODGSON and his spouse ELIZABETH J. DODGSON are residents of the State of New York, residing therein at 762 Powderhouse Road, Vestal, NY 13850.
2. Plaintiff ROSEANNA M. ROBINSON is a resident of the State of New York, residing therein at 82 Broad Avenue, Binghamton, NY 13904.
3. Upon information and belief, defendant GUIDANT CORPORATION is a foreign corporation incorporated under the laws of the State of Indiana, with its principal place of business at 111 Monument Circle, 29th Floor, Indianapolis, Indiana.
4. Upon information and belief, defendant GUIDANT SALES CORPORATION is a foreign corporation incorporated under the laws of the State of Indiana, with its principal place of business at 111 Monument Circle, 29th Floor, Indianapolis, Indiana, and is a wholly owned subsidiary of Guidant Corporation, and is doing business in the State of New York, and has its registered principal

office in the County of New York, with its process address at CT Corporation System, 111 Eighth Avenue, New York, NY 10011.

5. Upon information and belief, defendant CARDIAC PACEMAKERS, INC., also known as CPI-Guidant Corp., was at all times relevant hereto, or is a foreign corporation incorporated under the laws of the State of Indiana, is a wholly-owned subsidiary of defendant GUIDANT CORPORATION, and doing business in the State of New York.

6. Upon information and belief, in or about April 2006, Guidant's shareholders approved its acquisition by defendant Boston Scientific, and on April 21, 2006, as a result of the completion of said acquisition, Boston Scientific assumed all the liabilities of Guidant in connection with this litigation, and is legally liable for the wrongdoing of Guidant as it existed prior to the close of that acquisition.

7. At all relevant times, defendants Guidant Corporation, Guidant Sales Corporation, Cardiac Pacemakers, Inc., and Boston Scientific Corporation (hereinafter collectively referred to as "Defendants" or "Guidant") ; were and are present and doing business in the State of New York, transacted and conducted business and regularly do and/or solicit business within the State of New York, and derive substantial revenue from goods used and consumed in the State of New York.

8. At all relevant times, defendants expected or should have expected their acts to have consequences within the State of New York.

9. At all times relevant hereto, defendants were engaged in the business of manufacturing, marketing, promoting, selling and/or distributing, and placed in the stream of commerce a cardiac pacemaker medical device known as the Discovery II pacemaker, Model No. 1283 (the "product" or "pacemaker").

10. At all times herein mentioned, each defendant, itself or by use of others, did manufacture, create, design, test, label, package, distribute, supply, market, sell, advertise, or

otherwise distribute in interstate commerce said product.

11. Upon information and belief, each defendant engaged in advertising and promotional activity which indicated its product was efficacious and that it was safe to use, and based on defendants' promotional activity with respect to the aforesaid product, said product was implanted in plaintiff's body based on the belief the same was safe to use and was unlikely to subject plaintiff to serious danger or injury as a result of use of the product.

12. Defendants' aforesaid product was and is sold to hospitals and physicians for implantation into patients who are at risk for or have life-threatening ventricular arrhythmias, an electrophysiological change in the heart's rhythm resulting in a change in heart rhythm, which is life-threatening if the patient does not receive an electrical shock from an appropriate device.

13. Defendants' aforesaid product contains wires, called leads, inserted through a blood vessel and attached to the heart to detect irregularity in the heart's rhythm and deliver an electrical shock to prevent or terminate arrhythmia.

14. If defendant's product fails to operate as aforesaid, the patient will likely die unless medical intervention occurs within minutes.

15. On or about February 27, 2003, plaintiff Charles Dodgson underwent surgery for the implantation of a Guidant CONTAK RENEWAL pacemaker, Model No. H135, serial number 999351.

16. On or about December 27, 2005, plaintiff Charles Dodgson underwent surgery for the removal of the aforesaid defective Model No. H135 pacemaker, and for the implantation of a Guidant CONTAK RENEWAL 3 RF HE pacemaker, Model No. H219, serial number 200607.

17. In or about February, 2000, plaintiff Roscanna M. Robinson underwent surgery for the implantation of a Guidant PULSAR MAX pacemaker, Model No. 1170, serial number 102856.

18. In or about July 18, 2005, defendant Guidant Corporation voluntarily recalled several of

its pacemaker products, including the above models, due to the fact that a hermetic sealing component utilized in these devices may experience a gradual degradation, resulting in a higher than normal moisture content within the pacemaker case during the device's service life, which may lead to (a) premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning, (b) inappropriate accelerometer function if programmed ON, resulting in sustained pacing at the programmed maximum sensor rate (MSR), or lack of appropriate accelerometer rate response during activity with the aforesaid product as a component.

19. On or about July 22, 2005, the U.S. Food and Drug Administration (FDA) notified health care providers and patients that Guidant Corporation was voluntarily recalling certain pacemakers, including model 1283, citing a seal within the devices that can leak and allow moisture to affect the electronic circuits, causing the devices to fail to provide pacing or can cause a rapid heart rate, as well as possible other unexpected device behaviors, which may occur without warning and could lead to loss of consciousness, and possibly heart failure and death.

20. Plaintiff Charles Dodgson sustained a second surgery in December 2005 solely due to the defect in the Guidant Pacemaker implanted in 2003.

21. As a direct and proximate result of the aforementioned negligence of the defendants, injured plaintiffs sustained needless and severe pain and suffering.

22. As a direct and proximate result of the defendants' conduct, each injured plaintiff was caused to suffer and continued to suffer extreme mental and emotional distress and anxiety.

23. The defendants' conduct as aforesaid resulted in serious and permanent injury and future damages to the injured plaintiffs, including but not limited to the necessity of medical attention and hospitalization causing pain, agony, nervous shock, discomfort and anxiety.

24. By reason of the foregoing, injured plaintiffs sustained great pain and suffering, and continued to sustain great pain and suffering for a lengthy period of time, and sustained great anxiety

and fear of additional adverse medical consequences and premature death.

25. The injuries sustained by the aforesaid injured plaintiffs and the damages resulting therefrom were caused solely by the defendants' defective product without any fault on the part of the plaintiffs contributing hereto.

26. Plaintiffs allege that the limitations on liability set forth in CPLR § 1601 do not apply under the exemptions set forth in CPLR §§ 1602(5), 1602(7) and 1602(11).

**AS AND FOR A FIRST CAUSE OF ACTION
(NEGLIGENCE)**

27. Plaintiff incorporates by reference and reallege all preceding paragraphs 1 through 26 as if fully set forth herein and further allege the following.

28. Defendants breached their duty of reasonable care to injured plaintiffs.

29. The defendants knew or should have known with the exercise of reasonable care that the product was defective as aforesaid and as a result thereof modifications needed to be made in the hermetic sealing component that was susceptible to gradual degradation that was used in manufacturing the pacemaker product.

30. Defendants failed to obtain or perform timely and proper testing to evaluate or diagnose the problem with the hermetic sealing component.

31. Defendants were further negligent due to violating recognized and accepted standards of care in manufacturing the pacemaker product they provided to the injured plaintiffs.

32. The aforesaid conduct of the defendants was negligent, careless, reckless, and contrary to accepted good manufacturing practices.

33. Defendants knew or should have known with the exercise of reasonable care that the product was an unreasonably dangerous product and nevertheless manufactured and placed said product into the stream of commerce.

34. Prior to the time of the product's insertion in each injured plaintiff's body, defendants knew or should have known that a significant portion of the users of the product would be subject to a significant risk of danger of caused by the resulting behaviors of the defective hermetic sealing component.

35. The aforesaid conduct of the defendants was negligent and grossly negligent, and as a direct and proximate result of having the product inserted into their bodies, each of the injured plaintiffs was harmed as aforesaid.

36. As a direct and proximate result of defendants' malicious, reckless and/or negligent conduct, injured plaintiffs sustained emotional distress associated with the injuries.

37. Plaintiffs are entitled to compensatory and exemplary damages against the defendants jointly and severally.

**AS AND FOR A SECOND CAUSE OF ACTION
(STRICT LIABILITY - MANUFACTURING AND DESIGN DEFECT)**

38. Plaintiffs incorporate by reference and reallege all preceding paragraphs 1 through 37 as if fully set forth herein and further allege the following.

39. The product manufactured and/or supplied by defendants was defective in manufacture or construction in that when it left the hands of said defendants, it deviated in a material way from its manufacturing performance standards and/or differed from otherwise identical units manufactured to the same design formula.

40. The product manufactured and/or supplied by defendants was defective in design in that, when it left the hands of said defendants, the foreseeable risks exceeded the benefits associated with the design and/or formulation.

41. Alternatively, the product supplied by defendants was defective in design in that it was more dangerous than an ordinary consumer would expect when used in its intended or reasonably

forseeable manner.

42. As a direct and proximate result of the defective condition of the product, as manufactured and sold by said defendants, each of the injured plaintiffs was harmed as aforesaid.

43. Plaintiffs are entitled to compensatory and exemplary damages against the defendants jointly and severally.

**AS AND FOR A THIRD CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)**

44. Plaintiffs incorporate by reference and reallege all preceding paragraphs 1 through 43 as if fully set forth herein and further allege the following.

45. Defendants expressly warranted to injured plaintiffs that the product, which they designed, developed, manufactured and sold to injured plaintiffs, were of merchantable quality, fit and safe and otherwise not injurious to the plaintiffs' health and well being and would operate in the event of an arrhythmia to protect the plaintiffs by delivering an electrical shock to the heart.

46. Defendants expressly warranted that the product would monitor and record arrhythmia events and the operation of the device while it was implanted.

47. Defendants' representations formed part of the basis of the bargain and injured plaintiffs relied on said representations in deciding to have the product implanted.

48. The product implanted in injured plaintiffs was unsafe, unmerchantable, unfit for use in the body, otherwise injurious to the plaintiffs and did not operate as represented.

49. Through sale of the product, defendants were merchants pursuant to Section 2-314 of the Uniform Commercial Code.

50. Defendants breached express warranties of merchantability in the sale of the product to injured plaintiffs in that said product was not fit for its ordinary purposes described above.

51. As a direct and proximate result of defendants' breach of their express warranties as

described herein, injured plaintiffs suffered injury as alleged herein.

**AS AND FOR A FOURTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY)**

52. Plaintiffs incorporate by reference and reallege all preceding paragraphs 1 through 51 as if fully set forth herein and further allege the following.

53. Defendants are in the business of manufacturing and/or supplying and/or placing into the stream of commerce for consumers the product complained of.

54. By placing the product into the stream of commerce, said defendants impliedly warranted the product was of merchantable quality, was fit and safe for its intended use and was fit for the particular purpose of protecting the injured plaintiffs from cardiac arrhythmia.

55. The product placed into the stream of commerce by said defendants was unmerchantable, was not fit and safe for its intended use and not fit for the particular purpose intended.

56. The defects in the product manufactured and/or supplied by said defendants was present at the time the product left the hands of said defendants.

57. As a result, defendants breached implied warranties for the product because said product was defective, unmerchantable and not fit for its intended particular purpose.

58. Each of the injured plaintiffs was a foreseeable users of the product.

59. As a direct and proximate result of defendants' breach of implied warranties, each of the injured plaintiffs sustained harm.

**AS AND FOR A FIFTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)**

60. Plaintiffs incorporate by reference and reallege all preceding paragraphs 1 through 59 as if fully set forth herein and further allege the following.

61. Defendants falsely and fraudulently represented to the medical community and to the

injured plaintiffs that their product had been tested and found to be safe and effective for patients with heart disease.

62. The representations made by defendants were in fact false.

63. When said representations were made by defendants, they knew those representations to be false and/or willfully, wantonly and recklessly disregarded whether the representations were true.

64. These representations were made by the defendants with the intent of defrauding and deceiving the injured plaintiffs, the public in general, and the medical community in particular, to recommend, dispense and purchase the product, all of which evinced a callous, reckless, willful and depraved indifference to the health, safety and welfare of the injured plaintiffs.

65. At the time the aforesaid representations were made by the defendants, injured plaintiffs was unaware of the falsity of said representations and reasonably believed them to be true.

66. In reliance upon said representations, injured plaintiffs was induced and did use the product, thereby sustaining injury and damages.

67. As a direct and proximate result of defendants' malicious, reckless and/or negligent conduct, injured plaintiffs suffered harm as aforesaid.

AS AND FOR A SIXTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT WARRANTY)

68. Plaintiffs incorporate by reference and reallege all preceding paragraphs 1 through 67 as if fully set forth herein and further allege the following.

69. At all times during the course of dealing between defendants and injured plaintiffs, defendants misrepresented that the product was safe for its intended use.

70. Defendants knew that their representations were false, as defendants knew of problems with the model 1283 or components thereof malfunctioning prior to implantation and injury.

71. In representations to injured plaintiffs and by withholding defect information from the

FDA, thus preventing regulation, defendants fraudulent concealed and intentionally omitted the aforesaid material information, and that the product was not safe for use and susceptible to malfunction, that defendants were aware of the product's dangers, that the product was defective and the defect caused malfunction that rendered the device useless for a period of time with the potential to cause death and severe injury and emotional distress, that the product was manufactured negligently, that the product was manufactured defectively, and that the produce was manufactured improperly.

72. Defendants were under a duty to disclose to injured plaintiffs and their physicians, hospitals and medical providers, the defective nature of the product and/or the risks and dangers associated with it.

73. Defendants had sole access to material facts concerning the defective nature of the product and the defect and propensity to malfunction and cause serious and dangerous side effects, including death, and hence caused damage to injured plaintiffs.

74. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of the product, were made purposefully, willfully, wantonly and/or recklessly, to mislead injured plaintiffs and their physicians, hospitals and medical providers into reliance, continued use of the product, and actions thereon, and to cause them to purchase the product and/or have it implanted.

75. Defendants knew injured plaintiffs and their physicians, hospitals and medical providers had no way to determine the truth behind defendants' concealment and omissions, and these included material omissions of facts surrounding the product.

76. Injured plaintiffs, as well as their doctors, healthcare providers and/or hospitals reasonably relied on defendants' concealment and/or omissions of fact..

77. As a direct and proximate result of defendants' malicious, reckless and/or negligent conduct, injured plaintiffs suffered harm as aforesaid.

AS AND FOR A SEVENTH AND SEPARATE CAUSE OF ACTION
(SPOUSAL DERIVATIVE CLAIM)

78. Plaintiff's reallege and incorporate herein by reference all of the foregoing paragraphs 1 through 77, as if fully set forth herein.

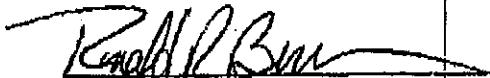
79. Plaintiff spouse Elizabeth J. Dodgson is and at all relevant times has been lawfully married to plaintiff Charles Dodgson.

80. By reason of the foregoing, plaintiff spouse has been deprived of the services and consortium of the injured plaintiff, including but not limited to companionship, affection, support and solace, and was caused to suffer a loss of enjoyment of life, all of which caused said plaintiff to be damaged and entitled to judgment against each defendant.

81. By reason of the foregoing, plaintiff spouse has incurred and been damaged with medical expenses and other expenses associated with his wife's injuries complained of herein.

WHEREFORE, plaintiffs respectfully request this Honorable Court to enter judgment against the defendants, jointly and severally, in compensatory damages, and exemplary damages if appropriate, in an amount to be determined by trial of this action, on each cause of action set forth herein, and that plaintiffs be awarded the costs and disbursements of this action, along with such other and further relief as is just and proper.

Dated: May 21, 2007



Ronald R. Benjamin, Esq.
LAW OFFICES OF RONALD R. BENJAMIN
Attorneys for Plaintiffs
126 Riverside Drive, P. O. Box 607
Binghamton, New York 13902-0607
607/772-1442